

APPLICATION FOR  
UNITED STATES LETTERS PATENT

SPECIFICATION

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TO ALL WHOM IT MAY CONCERN:

Be it known that I, Stan Batiste, a citizen of the United States of America, and resident of the State of Nevada, having a postal address of 808 Sir James Bridge Way, Las Vegas, NV, 89145, have invented a new and useful **"Improved A-V Dialysis Graft Construction"**, of which the following forms the specification.

## **"Improved A-V Dialysis Graft Construction"**

### **BACKGROUND OF THE INVENTION**

#### **CROSS REFERENCE TO RELATED APPLICATIONS**

Not applicable.

#### **5 Field of the Invention**

The present invention relates to the field of hemo-dialysis apparatus in general and in particular to an arterial-venous graft having an intra-graft stenosis formed integrally therein.

#### **Description of Related Art**

10 As can be seen by reference to the following U.S. Patent Nos. US 6,461,321 B1; 6,146,414; 5,713,859; 4,753,640; and, 4,549,879, the prior art is replete with myriad and diverse graft constructions employed for hemo-dialysis procedures.

While all of the aforementioned prior art constructions are more than adequate for the basic purpose and function for which they have been specifically designed, they  
15 are uniformly deficient with respect to their failure to provide a simple, efficient, and practical means of forming an artificial intra-graft stenosis to provide increased blood flow resistance during those periods when the higher blood flow rates required by hemo-dialysis are not present.

As virtually all physicians and health care specialists are aware, the process of  
20 hemo-dialysis requires large volumes of blood to be circulated through a filtration device. However, with prior art, A-V designs having a uniform bore configurations the

continued high pressure blood flow into veins creates venous irritation and scarring leading to "stenosis" and eventual occlusion as well as causing increased cardiac demands.

5 As a consequence of the foregoing situation, there has existed a longstanding need among medical personnel for a new and improved A-V stent graft construction having a reduced diameter portion, and the provision of such a construction is the stated objective of the present invention.

#### BRIEF SUMMARY OF THE INVENTION

10 Briefly stated, the improved A-V graft construction that forms the basis of the present invention comprises an elongated flexible tubular member having a generally uniform inside diameter with the notable exception of a reduced diameter intermediate portion which forms the crux of the present invention.

15 As will be explained in greater detail further on in the specification, in the first version of the preferred embodiment, the reduced diameter intermediate portion comprises a gently tapered segment having gradually diminishing and gradually expanding sections, and, in the second version of the preferred embodiment, the reduced diameter intermediate portion comprises an abruptly constricted section.

20 In addition, in both versions of the preferred embodiment, the average overall inside diameter of the generally uniform diameter tubular member is between 1/2 to greater than the average inside diameter of the reduced diameter 1/5 intermediate portion.

#### BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

25 These and other attributes of the invention will become more clear upon a thorough study of the following description of the best mode for carrying out the invention, particularly when reviewed in conjunction with the drawings, wherein:

FIG. 1 is a perspective view of the prior art uniform inside diameter A-V graft construction currently employed in hemo-dialysis procedures;

30 FIG. 2 is a representative perspective view of the A-V graft construction that forms the basis of the present invention;

FIG. 2A is an enlarged detail view of the smoothly constricted version of the invention;

FIG. 2B is an enlarged detail view of the abruptly constricted version of the invention; and,

FIG. 2C is an enlarged detail view of a hybrid version of the invention.

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## DETAILED DESCRIPTION OF THE INVENTION

As can be seen by reference to the drawings, and in particular to FIG. 2, the improved A-V graft construction that forms the basis of the present invention is designated generally by the reference number **10**. Prior to embarking on a detailed description of the improved graft construction **10**, it would first be advisable to describe the conventional graft construction **1** currently used as standard equipment in virtually all modern hemo-dialysis procedures.

As shown in Fig. 1, the prior art graft construction **11** includes an elongated length of hollow polymer tubing **12** having a uniform inside diameter extending from the inlet end **13** to the outlet end **14** wherein, the inlet end **13** defines the arterial anastomosis.

In addition, the conventional graft construction **11**, as well as, the improved graft construction **10** are commonly surgically placed within a patient's upper arm or forearm and connected via access needles **15 15** to a hemo-dialysis machine that withdraws blood from the arterial end **13** and removes impurities from the blood prior to re-introducing the cleansed blood through the venous end **14**.

As was mentioned previously, the hemo-dialysis procedure requiring abnormally high blood flow rates through the conventional uniform internal diameter graft constructions **11** and the presence of the conventional graft construction **11** allows the elevated blood flow rates to continue un-subsided during those periods when the access needles **15 15** are not connected to the hemo-dialysis machine **100**.

As a direct consequence of these elevated blood flow rates, increased cardiac demands are imposed on the heart as blood is bypassed past the distal circulation and the high pressure flow rates results in venous irritation leading to stenosis and occlusion which typically occurs at the venous anastomosis.

As a consequence of the foregoing situation, and as shown in Fig. 2, the improved graft construction **10** of the present invention includes an elongated length of

polymer tubing **12** having an inlet end **13**, and outlet end **14**, and a reduced diameter intermediate portion **16** which forms the heart of this invention.

In the first version of the preferred embodiment depicted in Fig. 2A, the intermediate portion **16** includes a gradually diminishing segment **16A** and a gradually expanding segment **16B** wherein, the minimum inside diameter of the intermediate portion **16** is equal to or less than  $\frac{2}{3}$  rds of the generally uniform inside diameter of the remainder of the length of polymer tubing **12**.

As can further be appreciated by reference to Fig. 2B in the second version of the preferred embodiment, the improved graft construction **10'** has a relatively abrupt reduced diameter intermediate portion **16'** created by a crimped segment **16C** in the length of polymer tubing **12**.

Furthermore, as depicted in Fig. 2C, this invention also contemplates a hybrid version including an abruptly crimped segment **16C'** that is selectively disposed upstream or downstream of a gradually expanding or diminishing segment **16A/B**.

Although only an exemplary embodiment of the invention has been described in detail above, those skilled in the art will readily appreciate that many modifications are possible without materially departing from the novel teachings and advantages of this invention. Accordingly, all such modifications are intended to be included within the scope of this invention as defined in the following claims.

Having thereby described the subject matter of the present invention, it should be apparent that many substitutions, modifications, and variations of the invention are possible in light of the above teachings. It is therefore to be understood that the invention as taught and described herein is only to be limited to the extent of the breadth and scope of the appended claims.